

SOUTH DAKOTA WHOLESALE & OTHER DRUG DISTRIBUTORS AND 503b OUTSOURCING FACILITIES RENEWAL APPLICATION INSTRUCTIONS

General Information

- License renewal period is November 1-December 31 each year.
- All licenses will expire December 31 each year. There is no grace period.
- For current South Dakota Statutes and Rules, go to <https://doh.sd.gov/boards/pharmacy/>, under Quick Links are law book link options.
- License fee is \$250 for all licenses except 503b is \$200.
- Payment methods – Mastercard or Visa **ONLY**.
- User ID and password must be unique for each licensed facility once license is approved/issued.

You must complete the entire application process from start to finish in one sitting

- Online system does not retain any information entered until the application has been submitted and payment process is complete.
- Have all of your information and copies of documents for upload ready before beginning the online application process.

Required Documents to be Uploaded

- PDF documents are preferred.
- Current home state license, its equivalent, or a written explanation why one is not available. (A primary source verification does not fulfill this requirement).
- Most recent home state, FDA, or VAWD inspection conducted within the last 4 years for this facility if home state is not SD. Explain if not available. Include deficiency correction documentation. 503b must provide an FDA inspection.
- Copy of Federal DEA certificate if dispensing controlled substances.
- If 503B Outsourcing Facility, FDA inspection report and deficiency correction documentation are required.
- If Virtual Manufacturer, provide:
 - 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
 - Contract Manufacturer name(s), address(es), and copy of agreement(s) first page and signature page only.
 - Product/NDC List
- If Virtual Distributor, provide:
 - 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
- A **list** of other state(s) entity is licensed in.
- Owner or Corporate Officer Certification, form can be found at <https://doh.sd.gov/boards/pharmacy/wholesalers.aspx>.

After Application Submission Information

After your application has been submitted, the Board will:

- Review the application
- Email licensing contact if additional information is needed
- Approve or deny the application

Once the new license is approved/issued, a profile account will need to be set up.

- Instructions to set up a profile account are at the end of this manual (beginning on page 10)
- For the profile account, a unique User ID and password for *each* licensed pharmacy will need to be established.
- Retain User ID/password to have ability to access the licensing platform when needed.

After the license is approved/issued and the profile account is set up, you will be able to do the following:

- To check application status
- Print facility license (instructions on page 12)
- Print a payment receipt (instructions on page 12)

Licensure status can also be verified at:

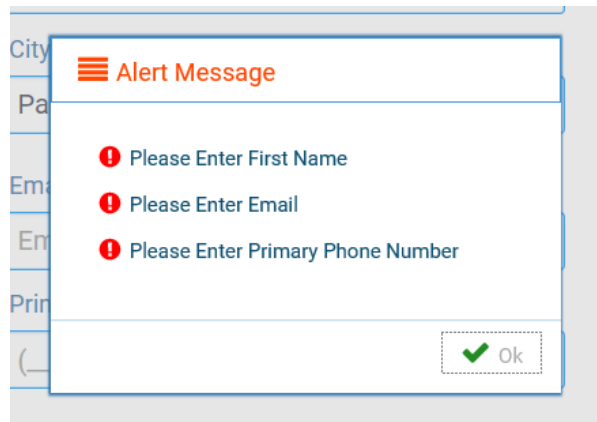
- Verification page: <http://doh.sd.gov/boards/pharmacy/verification.aspx>

For Troubleshooting Tips click on this link and click on the Troubleshooting Tips document:

<https://doh.sd.gov/boards/pharmacy/wholesalers.aspx>.

General Notes

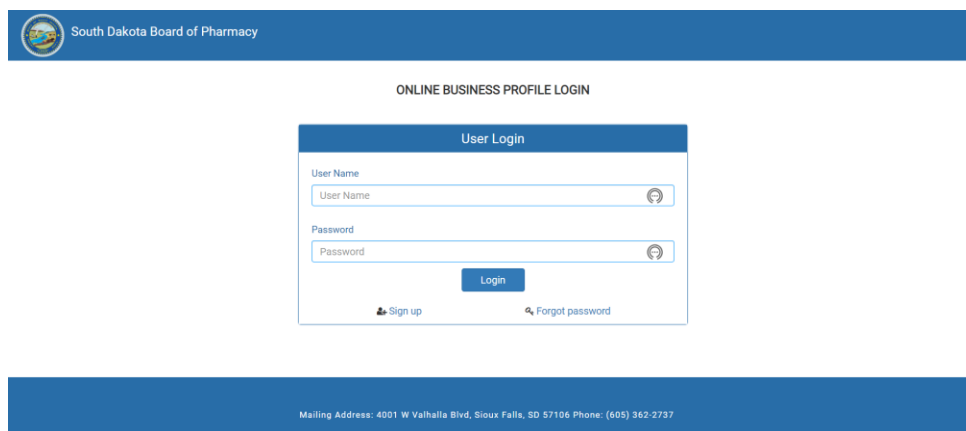
1. Mandatory fields are marked with a red * in all screens and all those have to be entered before clicking on next
2. If mandatory fields are not entered, you will get an alert message that alerts to enter those fields like below:



START RENEWAL PROCESS HERE

Profile

1. Click on this link (**Bookmark this page**):
https://sdbop.igovsolution.com/online/User_login.aspx
 - a. **If this is the first time this license has been renewed**, click on sign up and follow the next steps.
 - b. **If this is not the first time this license has been renewed**, skip to step 3.2 and enter your user name and password used in a previous renewal.

The image shows a screenshot of the South Dakota Board of Pharmacy's online business profile login page. At the top is a blue header with the South Dakota Board of Pharmacy logo and name. Below the header, the text "ONLINE BUSINESS PROFILE LOGIN" is centered. The main content area features a "User Login" form with two input fields: "User Name" and "Password", each with a red eye icon for toggling visibility. Below the fields is a blue "Login" button. At the bottom of the form are links for "Sign up" and "Forgot password". A footer bar at the bottom contains the mailing address: "Mailing Address: 4001 W Valhalla Blvd, Sioux Falls, SD 57106 Phone: (605) 362-2737".

2. Click Sign Up and in the Registration screen input the permit type from the drop-down, enter the last four digits of the permit number, and enter the zip code of the facility. This information must match what is on your current license/permit. Click Next.

ONLINE BUSINESS PROFILE

Registration

Step 1 / 2

Please provide the information below.
[Click here to verify your Permit #.](#)

* Permit Type

Wholesale

* Permit #

600-0004

* Physical Zip

11788

Next

[? Forgot Password](#)

3. On the Credentials Page, enter the credentials in the below screen and click Submit. There are no password guidelines or restrictions.

Credentials

Step 2 / 2

* Email

roy@igovsolution.com

* Confirm Email

roy@igovsolution.com

* User Name

TestRoy

* Password

* Confirm Password

Previous

Submit

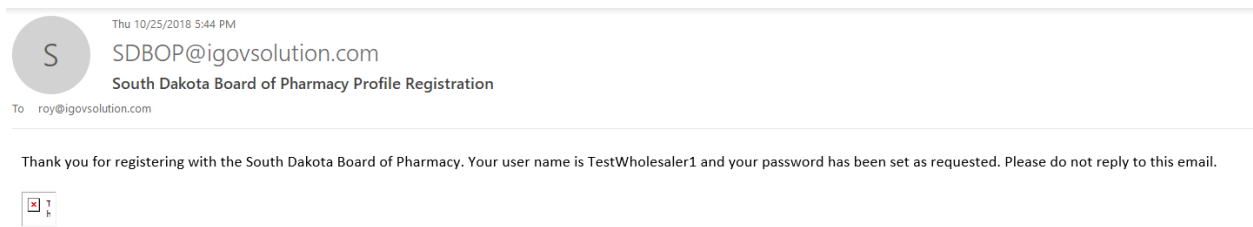
Alert Message

!

User registration successful.

Ok

3.1 Once user registration is successful an e-mail will be triggered to the e-mail that you provided during your registration, like below:



3.2 Return to the User Login page and input the user id and password to login used to set up the account and you will be directed to the My Profile page like below:

A screenshot of the "User Login" form. It has a blue header with the text "User Login". Below the header, there are two input fields: "User Name" with the value "TestWholesaler1" and "Password" with a masked value "*****". Both fields have a circular icon with a right arrow on the right side. Below the password field is a blue "Login" button. At the bottom of the form, there are two links: "Sign up" with a person icon and "Forgot password" with a magnifying glass icon.A screenshot of the "My Profile" page. The page has a blue header with the South Dakota Board of Pharmacy logo and the text "South Dakota Board of Pharmacy". Below the header is a "My Profile" button. The main content area is titled "Business Profile Information" and contains a form with the following fields: "Business Name" (KREMERS URBAN PHARMACEUTICALS INC), "DBA" (dba LANNETT COMPANY INC), "Responsible Person" (STEVE VOELZ), "License Type" (Wholesale), "Ownership Type" (C), and "Title" (DISTRIBUTION MANAGER). There is an "Edit" button in the top right corner of the form.

3.3 In the My Profile page you can edit the information:

- **Business Profile Information:** In this section the Name of the business, License type, Ownership Type, DBA, Responsible person, Title are captured. And only Ownership type, DBA, Responsible person, Title fields are editable.

A screenshot of the "Business Profile Information" form, showing the same fields as the previous screenshot. In this version, the "Ownership Type" (C), "Responsible Person" (STEVE VOELZ), and "Title" (DISTRIBUTION MANAGER) fields are highlighted with a blue border, indicating they are editable. There are "Save" and "Cancel" buttons at the bottom of the form.

- **Registration Information:** This section contains the License information details like, Type, License#, Issue date, Exp. Date, status, Last renewal date, Renewal. These are non-editable fields. The Renew button used to Renew the license and it takes you to Renewal webpage. Licensee can also able to print their Licenses/registration information from here by clicking on the Print button

Registration Information

Type	License #	Issue Date	Exp Date	Status	Last Renewal Date	Renewal	Certificate
Filters	Filters	Filters	Filters	Filters	Filters		
Wholesale	600-0000	10/31/2014	10/31/2019	Current/Active	10/31/2018		Print

- **Primary Address section:** This is the Physical location of the business i.e. the address in the Business information / demographics section. All the fields are editable
- **Mailing address information:** This is the mailing address information, if this is different from the physical address location and this is the address that is being used to send the certificate to the business. These are editable fields.
- **Contact Information:** This section contains the phone number, e-mail, fax etc. of the business. These are editable fields.
- **Document details:** This section contains all the documents uploaded as part of the Renewal, also this section can be used if the licensee would like to upload any additional documents by using the correct document type from the Document type drop down list, use the attach document to select / browse the file from the local folder and then use the Upload document. Any documents that uploaded / showing in this Documents section can also be downloaded
- **Renewal Details:** In this section licensee can check the status of their Renewal application – if it's Pending or if it's Cleared. If it's Cleared, then in the Registration information grid will show the updated license expiration date, Last renewal date. Also, you can print your online submitted Renewal form, if needed. **Note:** this is a receipt that iGov is generating with the information we have, that will be shown in the profile section. This is not the full receipt from Elavon, they need to be emailing that as providers in other states do.

Renewal Details

Order ID	License Number	Renewal Date	Status	E-Signature	Print
Filters	Filters	Filters	Filters	Filters	
20181027000000001	600-0000	10/27/2018	Cleared	Test Wholesaler	Print
20181027000000002	600-0000	10/27/2018	Pending	Test Wholesaler	Print

APPLICATION BEGINS HERE

1. After validating all the information in the My Profile section, click on the Renew icon in the profile section under the Registration Information section.

Registration Information

Type	License #	Issue Date	Exp Date	Status	Last Renewal Date	Renewal
Filters	Filters	Filters	Filters	Filters	Filters	
Wholesale	600-0000	10/31/2014	10/09/2018	Current/Inactive	10/10/2017	Renew

2. After clicking on the Renewal icon click on the confirmation message

Confirmation Message

By continuing to renew my license/registration, I affirm that I have reviewed all the sections of my profile and the information in my profile is accurate.

☒ Yes
 ☐ No

3. It will take you to the Renewal screen where it will show the Instruction link, Demographics (Physical location of the business), Type of Distribution (for Wholesaler), Type of Prescription (for Wholesaler), Types of Customers you sell / distribute (for Wholesaler), Ownership (for Wholesaler), and other relevant pages for Wholesaler.
4. **Demographics** – this is the Physical location of the Business / permit. Provide the Responsible Person information. The rest of the section is non-editable.

Demographics

Legal/Business Name
SD Test W1

DBA
SD TEST W1 DBA

License #
600-0000

Address1
123 Medicine Drive

Address2
Address2

Address3
Address3

City
BRANDON

State
SD

County
MINNEAPOLIS

Zip
57005

* Name of Responsible Person at Firm
Name of Responsible Person

* Email of Responsible Person at Firm
Email of Responsible Person at Firm

* Phone number of Responsible Person at Firm
() - -

Please review the information in the section above. If the Name and License # do not belong to this facility, please contact the Board immediately.

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 Next

5. **Type of Distribution** – This section is the Types of Distribution. These are Multi select fields:
 - a. If selecting Manufacturing Distributor, 503B Outsourcing Facility then you will get an option to enter the FDA# which is a Mandatory field

Type of Distribution

☐ Wholesale Distributor
 ☐ Manufacturing Distributor
 ☐ Repackager
 ☐ Reverse Distributor

☒ 503B Outsourcing Facility
 ☐ Virtual Manufacturing
 ☐ Virtual Distributor
 ☐ In State Only - Third Party Logistics Provider

☐ Distribution Center
 ☐ Other

* FDA #
 FDA #

- b. If selecting Virtual Distributor then the option to enter the 3PL details will populate, where you can enter the Name, Address, City State Zip for the 3PL. Also, there are mandatory upload fields for uploading Copy of 3PL agreement, first page along with Signature page, 3PL VAWD accreditation.

Type of Distribution (Check all that apply)

☐ Wholesale Distributor ☐ Manufacturing Distributor ☐ Repackager ☐ Reverse Distributor
☐ 503B Outsourcing Facility ☐ Virtual Manufacturing ☒ Virtual Distributor
☐ Distribution Center ☐ Other

3PL details

* Name of Business:
 * Address1: Address2: Address3:
 * City: * State: * Zip:
 Copy of 3PL agreement, first page, along with signature page
 3PL VAWD accreditation upload

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- c. If selecting Virtual Manufacturing option then you will get the option to enter the 3PL details (name, address, city, state, county, zip) along with mandatory upload options for copy of agreement first page, Signature page, 3PL VAWD accreditation, product list. Also, see the option to upload Contract Manufacturer options. If you need to add more than one contract manufacturer's details, then use the 'Click here to add more Contract manufacturers' button and save.

Type of Distribution (Check all that apply)

☐ Wholesale Distributor ☐ Manufacturing Distributor ☐ Repackager ☐ Reverse Distributor
☐ 503B Outsourcing Facility ☒ Virtual Manufacturing ☐ Virtual Distributor ☐ In State Only - Third Party Logistics Provider
☐ Distribution Center ☐ Other

3PL details

* Name of Business:
 * Address1: Address2: Address3:
 * City: * State: * Zip:
 Copy of 3PL agreement, first page, along with signature page
 3PL VAWD accreditation upload
 To add more 3PL Details, please click the button provided here. [Click here to add more 3PL details](#)

Contract Manufacturer

* Name of Business:
 * Address1: Address2: Address3:
 * City: * State: * Country: * Zip:
 Copy of Contract Manufacturer Agreement (CMA) first page along with Signature page
 Product / NDC list
 To add more Contract Manufacturers, please click the button provided here. [Click here to add more Contract manufacturer](#)

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- d. If option selected as Other, then an option to enter the explanation with text box will appear which is a Mandatory field

Type of Distribution

☐ Wholesale Distributor ☐ Manufacturing Distributor ☐ Repackager ☐ Reverse Distributor
☐ 503B Outsourcing Facility ☐ Virtual Manufacturing ☐ Virtual Distributor ☐ In State Only - Third Party Logistics Provider
☐ Distribution Center ☒ Other

* Other

Note: If the license is Out of State i.e.: (out of South Dakota) then you will not see the In State Only – Third Party Logistics provider option under Type of Distribution tab

Type of Distribution (Check all that apply)

☐ Wholesale Distributor ☐ Manufacturing Distributor ☐ Repackager ☐ Reverse Distributor

☐ 503b Outsourcing Facility ☐ Virtual Manufacturing ☐ Virtual Distributor ☐ In State Only - Third Party Logistics Provider

☐ Distribution Center ☐ Other

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6. **Type of Prescription Drugs/Products:** this is a multi-select options.

- a. If you select DEA controlled substance, then you will get 2 Mandatory fields i.e.: DEA and Controlled substances#

Type of Prescription Drugs/Products

☒ DEA Controlled Substance ☐ Ephedrine or pseudoephedrine products ☐ Noncontrolled prescription drugs (federal legend)

☐ Over-the-counter drugs ☐ Veterinary prescription drugs ☐ Medical Gases

☐ Other

* DEA # RC0208149 * Controlled Substance # RC0208149SD

Copy of current Federal DEA Certificate Attach Document

If registration is needed, contact the SD Dept. of Health, Attn: Licensure & Certification, 615 E 4th St, Pierre, SD 57501 for information regarding SD controlled substance registration. Phone 605-773-3356 or download application from <http://doh.sd.gov/providers/assets/applab.pdf>

- b. If selected option Other, then you will get a field for Explanation text box

Type of Prescription Drugs/Products

☐ DEA Controlled Substance ☐ Ephedrine or pseudoephedrine products ☐ Noncontrolled prescription drugs (federal legend)

☐ Over-the-counter drugs ☐ Veterinary prescription drugs ☐ Medical Gases

☒ Other

* Enter Explanation

Enter Explanation

7. **Types of Customers you sell / distribute:** this is a multi-select options field. If the option Other selected, then you will get a field to enter explanation

Types of Customers you sell/distribute (Check all that apply)

☒ Pharmacies ☒ Hospitals ☒ Other Wholesalers

☒ Practitioners/Clinics ☒ Patients ☒ Other

* Enter Explanation

Enter your explanation here

8. **Ownership:** This is Single select option field.

- a. If selected Sole proprietorship, then you will get the fields to enter values for Name, Address, City, State, Zip, County. All these fields are Mandatory
- b. If Partnership option is selected, then use the Click Here to add more button to enter the Name and address of the Partnership, this window consists of Business Name, Address (lines 1, 2, 3), city, state, zip. And click Save button. All these fields are mandatory

Ownership

☐ Sole Proprietorship ☒ Partnership ☐ Corporation ☐ LLC ☐ Other

Name and Address of Partnership [Click Here To Add More](#)

Attach Name and Address of Partners

Name and Address Of Partnership

* Business Name
Business Name

Address2
Address2

* City
City

* Zip
Zip

* Address1
Address1

Address3
Address3

* State
Select State

Save Cancel

Previous Next

c. Use the Attach document to upload name and address of the partners

Ownership

☐ Sole Proprietorship ☒ Partnership ☐ Corporation ☐ LLC ☐ Other

Name and Address of Partnership [Click Here To Add More](#)

Attach Name and Address of Partners [Attach Document](#)

Please include the Name and Address of Partner/Officer/Member

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d. If option Corporation is selected then you will get the below option to enter fields, Name of Corporation, Address 1, City, State, Zip fields are mandatory

Ownership

☐ Sole Proprietorship ☐ Partnership ☒ Corporation ☐ LLC ☐ Other

Name and Address of Corporation [Click Here To Add Corporation](#)

Attach Name and Address of Corporate Officers

Corporation

* Name Of Corporation
Name of Corporation

Address2
Address2

* City
City

* Zip
Zip

* Address1
Address1

Address3
Address3

* State
Select State

Save Cancel

Previous Next

e. If option LLC is selected then you will get the option to enter the Name and address of the LLC, to attach the name and members list use the attach document button

f. If option of Other selected, then you will get a field to enter the explanation in the text box

Ownership

☐ Sole Proprietorship ☐ Partnership ☐ Corporation ☒ Other

* Enter Explanation

Enter Explanation

9. **Registered Agent in SD – Note:** this option / page will only appear if the license is out of South Dakota. All the fields are mandatory. Also, if user want to see the list of the SD registered agents they can click on the link.

Registered Agent in SD

* Name
Name

* Address1
Address1

Address2
Address2

Address3
Address3

* City
City

* State
Select State

* County
Select County

* Zip
Zip

For a list of SD registered agents go to https://sdsos.gov/docs/business/CRA_list.pdf

10. **Home State License – Note:** this option / page will only appear if the license is out of South Dakota. Home state, Home state license#, License expiration date fields are mandatory. Also, the attachment is mandatory for uploading the Home state license, Inspection document. The Home state is a drop-down list, Inspection type is also a drop-down list. SDBoP only accepts Inspections which are conducted from January 1, 2014 onwards, prior to this date the system will not allow you to enter and proceed. If the 'no inspection' option is selected, upload a document stating the reason of no inspection. If answer is Yes to the question "were there any deficiencies in the inspection identified above?" then you need to upload the inspection correction documents also. **Note:** If Type of Distribution is 503b then the type of distribution will default to FDA inspection.

Home State License

Home State License

* Home State
Select State

* Home State License#
Home State License#

* License Expiration Date
MM/DD/YYYY

DEA #
DEA #

FDA #
FDA #

Home State License
Home State or Other Inspection

Type of Inspection
Select Type of Inspection

Date of most recent inspection
MM/DD/YYYY

Were there any deficiencies in the inspection identified above?
☐ Yes ☐ No

Inspection document (If there is no inspection, please upload a document stating reason why there is none)

Previous

Attach Document

Next

- a. **VAWD:** If VAWD accredited, then select the option Yes, and enter the VAWD accreditation expiration date. Also, enter a list of all other states where licensed in. **Note:** Please use comma to enter the values or if uploading a list, write 'see attached' in space. List of states can be uploaded in the next section titled Attachments.

VAWD

VAWD Accredited?
☐ Yes ☐ No

VAWD Accreditation Expiration Date
MM/DD/YYYY

* Provide a List of All States Licensed In (Use comma to type out multiple states. Please note that there is an option to upload the list of states in the Attachments section at the end. If you prefer to do that, please type "See Attached" in the box below.)
Other States Licensed In

11. **Attachments** – upload to this section the mandatory document, ‘Owner or Corporate Officer Certificate Form’, and optional list of all other states licensed in. The Owner or Corporate Officer Certification Form must be signed with original ink or an e-signature will be accepted that is similar to E-Signature by Adobe Sign. If a power of attorney is being used, the power of attorney documents must be provided with the Owner or Corporate Officer Certificate Form.

The screenshot shows the 'Attachments' section of the application form. It has a blue header with the title 'Attachments'. Below the header, there are two rows of information. The first row contains the text 'Owner or Corporate Officer Certification Form. Please refer the link below for more details.' followed by the URL 'http://doh.sd.gov/boards/pharmacy/wholesalers.aspx' and an 'Attach Document' button. The second row contains the text 'List of all States licensed in' and another 'Attach Document' button.

12. **Disciplinary Actions** – This is the section pertinent to the disciplinary question, if answered ‘Yes’, then option to enter explanation and/or upload explanation document will be available. If no, then you move to the next step/page.

The screenshot shows the 'Disciplinary Actions' section of the application form. It has a blue header with the title 'Disciplinary Actions'. Below the header, there is a question: 'Have any misdemeanor or felony convictions or disciplinary actions (including pending) been taken against the applicant or the facility in the last 7 years?' with 'Yes' and 'No' radio buttons. Below the question is a text area for 'Please enter relevant explanation'. To the right of the text area is an 'Attach Document' button.

13. **Application Preview** – This is where you can review the application before submitting

The screenshot shows the 'Application Preview' section of the application form. It has a blue header with the title 'Application Preview'. Below the header, there is a section titled 'Instructions' with a scroll bar on the right. The instructions include information about renewals, general information, and documents needed for renewal. At the bottom of the instructions section are 'Previous' and 'Next' buttons.

You can scroll the bar on the right to go to the bottom of the application preview page.

14. **Affirm and Submit** - Select the checkbox to certify and it will show the name of the licensee and E-signature. Once you click Proceed to pay, it will take you to the Payment page in the Affirm and Submit page (Last step). **Note: Only Mastercard and Visa are accepted.** All the fields are mandatory. Once successfully submitted you will get a System generated auto reference number. If needed/required, make note of that System generated auto reference number for your future reference.

Affirm and Submit

☐ I certify that the applicant will operate in a manner prescribed by federal and state laws and rules adopted by the board. I declare and affirm under the penalties of perjury that this application has been examined by me, and to the best of my knowledge and belief, is in all things true and correct.

* E-Signature of the person filling out this renewal (Type in full name)

* Date

* Renewal Fee

* Select Debit or Credit :

* Card Type

* Person's Name on Card

* Card #

* Expiration Date (MM/YY)

* Security Code

[Previous](#) [Submit](#)

Please note that after you click the Submit button, you cannot make changes to your application.

15. Once your online renewal has been completed, check the progress of your renewal, or print your license, log back into your account. To check the status of your renewal, look in the registration Information section under the 'Status' column. Once your renewal is approved, to print your certificate, in the registration information section under the 'Certificate' column, click on Print.

Registration Information

Type	License #	Issue Date	Exp Date	Status	Last Renewal Date	Renewal	Certificate
Filters	Filters	Filters	Filters	Filters	Filters		
Wholesale	600-0000	10/30/2018	12/31/2018	Current/Active	10/30/2018	Renew	Print

16. To print a receipt, on the My Profile page scroll down to the Payment History section, click on the small printer under the receipt column to the right for the receipt desired.

Payment History

Receipt #	Payment Method	Date Received	Payor	Amount	Receipt
Filters	Filters	Filters	Filters	Filters	
201904306	Credit Card	04/30/2019	0000	\$200.00	